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Docket No.: 19240.145-US2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Edward F. Leonard et al.

U.S. Serial No.: 10/801,366

Confirmation No.: 3154

Filed: March 15, 2004

Art Unit: 1723

For: Systems and Methods of Blood-Based Therapies  
Having a Microfluidic Membraneless Exchange  
Device

Examiner: John Kim

**REPLY TO DECEMBER 2, 2005 OFFICE ACTION**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This paper is submitted in reply to the December 2, 2005 Office Action (Restriction Requirement). A reply was due January 2, 2006. Since January 2, 2006 was a Federal Holiday, a reply is due today, January 3, 2006, and this reply is being timely filed.

The Examiner required applicants to elect a group of claims for examination. In reply, applicants elect Group II, claims 21-37, with traverse.

The basis for the restriction alleged by the Examiner was that the groupings "are directed to a method or apparatus for using membraneless exchange device, but each group has a different special technical feature not shared by the remaining groups." (See Office Action, page 3.) Applicants respectfully submit that the claims of Groups I-III should be examined together, since they share a relationship involving the use of a device that includes inlet channels and exit channels and a dialysis or extraction channel and because it would not present an unreasonable task for, or place an undue burden on, the Examiner for searching purposes to examine the claims of these groups together.

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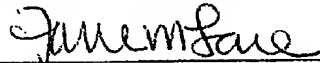
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The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 08-0219.

Dated: \_\_\_\_\_

1/3/06

Respectfully submitted,



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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20 and 38-40, drawn to a membrane exchange device for extracting components from a sample fluid comprising first, second and third inlet channels, first, second and third exit channels and a microfluidic extraction channel connected to the first, second and third inlet channels and the first, second and third exit channels.

Group II, claims 21-37, drawn to a system for performing hemodialysis comprising a membraneless exchange device comprising of first, second dialysate inlet channels, blood inlet and exit channels, first and second dialysate exit channels and a microfluidic dialysis channel connected to the first and second dialysate inlet and outlet channels and the blood inlet and exit channels and a secondary processor that receives the dialysate fluid and the at least some of the components of the blood fluid exiting the device through the first and second dialysate exit channels.

Group III, claims 41-43, drawn to a method for performing hemodialysis comprising the step of establishing laminar flows of a first dialysate fluid, blood fluid and a second dialysate fluid inside a microfluidic extraction channel and withdrawing the first dialysate fluid, the blood fluid and the second dialysate fluid from the extraction channel.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: All of the groupings are directed to a method or apparatus for using membraneless exchange device, but each group has a different special technical feature not shared by the remaining groups. Group I is directed to an apparatus which has the special technical feature of first, second and third inlet channels, first, second and third exit channels and a microfluidic extraction channel connected to the first, second and third inlet channels and the first, second and third exit channels not shared by any of the remaining groups.

Group II is directed to an apparatus which has the special technical feature of first, second dialysate inlet channels, blood inlet and exit channels, first and second dialysate exit channels and a microfluidic dialysis channel connected to the first and second dialysate inlet and outlet channels and the blood inlet and exit channels and a secondary processor that receives the dialysate fluid and the at least some of the components of the blood fluid exiting the device.

through the first and second dialysate exit channels not shared by any of the remaining groups.

Group III is directed to a method which has the special technical feature of the step of establishing laminar flows of a first dialysate fluid, blood fluid and a second dialysate fluid inside a microfluidic extraction channel and withdrawing the first dialysate fluid, the blood fluid and the second dialysate fluid from the extraction channel without separate inlet channels or exit channels not shared by any of the remaining groups.

A telephone call was made to Dr. Jane Love on 11/28/05 to request an oral election to the above restriction requirement, but did not result in an election being made. Dr. Love requested a written restriction.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
November 28, 2005